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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/203,672	02/28/1994	BRIAN H. SILVER	5297/32	1958

7590

09/25/2002

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EXAMINER

TRINH, HOA B

ART UNIT

PAPER NUMBER

2814

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/203,672

Applicant(s)

SILVER ET AL. 

Examiner

Vikki H Trinh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-14 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-14 and 19 is/are allowed.
- 6) ☒ Claim(s) 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 22 is objected to because of the following informalities: The writing area shown in figures 1-5 only indicates legibly the information such as name, time, and date. However, applicant claims that the writing area also includes a second area for indicating the volume of the breast milk in the enclosure. Because there appears to be no legible or visible label in the figures 1-5 with the term "volume", the examiner assumes, in order to expedite the prosecution process of this application, applicant has intended to state that the writing area is "capable" of including the information such as the volume of breast milk in the enclosure as well. Appropriate correction is required.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "second area for indicating a volume of breast milk" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

An anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. See *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984).

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It is well settled that the law of anticipation does not require that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e., all limitations of the claims are found in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. See, for example, *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ2d 1321 (Fed. Cir. 1991).

2. Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham ((3,905,477)).

With respect to claim 20, Graham (3,905,477) discloses a disposable bag 11 which is permanently sealed except at one portion at the top end closure 25 thereof. The portion comprises a bag access 29 adapted to substantially seal the bag in a first position thereof by a plug or clamp means but also adapted to selectively allow in a second position thereof the liquid to be introduced in the chamber/enclosure 27 having a front side 13 and a back side 15, a seal 19 to seal the front 13 and the back side 15 together, and a section or a writing area 23, wherein the writing area 23 forms integral with the bag 11 by the seal 9 and isolates or remotes from a liquid containing portion or enclosure 27. (See figure 1 and column 3, lines 16-43.)

The examiner notes that breast milk is a type of liquid/fluid which may be considered as viable and perishable material. Additionally, the recitation "A bag adapted to contain beast milk" in the preamble denotes an intended use which does not structurally distinguish over the prior art of record. A preamble is generally not accorded any patentable weight where it merely

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recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

As to claims 21-22, the section 23 comprises at least first area indicating thereon a date of filling the enclosure 27. The writing area or section 23 may also be inherently used for information such as the "volume" of the content inside of the bag. (See figure 1.)

As to claim 23, the bag is made from a plastic tube permanently closed at a lower end thereof by a lower seal 19 thereby delimiting a bottom end of the enclosure 27, the section 23 extending from the lower seal 19 away from the enclosure 27. See figure 1 and column 3, lines 16-43.

3. Claims 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanase (4,600,104)

As to claim 25, a method of substantially sterile handling breast milk, comprising the steps of a) providing a closed disposable sterile bag 1 comprising a tear off strip 9 and providing a bag holder which is a breast pump (unlabeled); b) removing said tear off strip to reveal a milk receiving chamber (unlabeled) of said bag 1; and c) mounting said bag 1 to said bag holder/breast pump (unlabeled); wherein milk is introduced in said chamber between said steps b) and c) or after step c). (See Yanase '104, column 3, lines 4-33.)

As to claim 26, a method as defined in claim 25, wherein after step b), said bag 1 is attached to a breast pumping device (unlabeled) such that breast milk retrieved by said pumping device is directly delivered through into said bag 1. (See Yanase '104, column 3, lines 4-33.)

**Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanase (4634006) in view of Graham (3905477).

Yanase (4634006) discloses the invention substantially as claimed. Yanase (4634006) discloses a disposable bag 1 for containing breastmilk. The bag 1 comprises an enclosure defining a chamber adapted to contain therein breast milk. The bag 1 is hermetically sealed, except at one portion 9 which comprises a bag access adapted to substantially seal the bag in a

first position by also adapted to selectively allow in a second position thereof the breast milk to be introduced in the chamber when it is desired to be used, whereby once in the second position the breast milk can be received in the bag. (See figures 1, the abstract, column 1, line 42, column 3, lines 4-69, and column 4, line 1.)

However, Yanase does not explicitly teach a section locates remote from the enclosure and adapted for receiving thereon information about the content of the bag 1.

Graham (3,905,477) discloses a bag 11 having a seal 19, a front side 13 and a back side 15, liquid filling compartment/enclosure/chamber 27, and a writing area 23, wherein the writing area 23 forms integral with the bag 11 by the seal 9 joining the front and back inboard of the bag perimeter in facial engagement to define the writing area 23. The writing area 23 is isolated or being remote from a liquid filling/containing portion 27. (See figure 1 and column 3, lines 16-43.)

Yanase and Graham are analogous art, because they are in the same field of endeavors.

Therefore, with respect to claim 20, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the writing area in Yanase with the writing area, as taught by Graham, for identifying the content inside the bag.

As to claims 21-22, the combined teaching of Yanase in view of Graham includes the section 23 comprising at least first area indicating thereon a date of filling the enclosure 27. The writing area or section 23 may also be used to include the information such as the "volume" of the content of the bag. (See Graham's figure 1.)

As to claim 23, the combined teaching of Yanase in view of Graham includes the bag being made from a plastic tube permanently closed at a lower end thereof by a lower seal 19 thereby delimiting a bottom end of the enclosure 27, the section 23 extending from the lower seal 19 away from the enclosure 27. (See Graham's figure 1 and column 3, lines 16-43.)

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As to claim 24, the combined teaching of Yanase in view of Graham includes the bag in combination with a bag holder 34, 36, said bag holder 34, 36 comprising a hollow body 30 and a cap 34 provided with a nipple 33 and being adapted for feeding a baby, said bag holder being adapted for receiving therein said bag. (See Yanase '104, column 3, lines 4-33, which incorporated Yanase (3,977,405) entirety - figure 8.)

The courts have concluded that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). Also, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

#### *Allowable Subject Matter*

Claims 8-14, 19 are allowed.

#### *Conclusion*

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikki H Trinh whose telephone number is 703-308-8238. The examiner can normally be reached on Mon.-Tues, Thurs.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Olik Chaudhuri can be reached on 703-306-2794. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-77224 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.



Vikki Trinh  
September 22, 2002



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